IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
(HOUSTON DIVISION)

GAYATHRI MURTHY, Plaintiff,	§ § §	
v.	§	CASE #: 4:11-cv-00105-KPE
ABBOTT LABORATORIES, Defendant.	§ § §	

PLAINTIFF'S RESPONSE IN OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT ON FAILURE-TO-WARN AND BREACH-OF-CONTRACT CLAIMS

Respectfully submitted,

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Table of Contents

Table of Authorities

Cases **Page(s)**

Statutes, Legislative History and Rules **Page(s)**

Other **Page(s)**

Abbott's Motion for Summary Judgment on Failure-To-Warn and Breach-of-Contract Claims [hereinafter "Abbott's MSJ"] is a predictable, and rather bombastic pleading that, along with its sister papers, threatens to overwhelm the Court. This particularly motion is not only over-length, but is equally a not-so-subtle usurpation of the record. Regardless, because many of the issues and arguments contained in Abbott's MSJ have already been addressed in Plaintiff's own Motion for Partial Summary Judgment [hereinafter "Plaintiff's MPSJ"], Plaintiff will do her best to be respectful of the Court's time and resources and not reiterate arguments that are already before the Court. Rather, she will limit her response to addressing Abbott's arguments. She apologies for the overlap that is inevitable. As such, Plaintiff expressly incorporates all related briefing and exhibits.[1]

Argument and Authorities

I. SUMMARY JUDGMENT STANDARDS.

The Court is obviously well versed in federal summary judgment standards. Briefly, Abbott, as the movant, bears the burden of demonstrating that there is no actual dispute as to any material facts. FED. R. CIV. P. 56(a), *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). A genuine issue of material fact exists if a reasonable jury could enter a verdict for the non-movant. *Crawford v. Formosa Plastics Corp.*, 234 F.3d 899, 902 (5th Cir. 2000). The court is not permitted to make credibility determinations regarding the evidence. *Lindsey v. Prive Corporation*, 987 F.2d 324, 327 (5th Cir. 1993). And this Court must view all evidence in the light most favorable to the non-moving party and draw all reasonable inferences in that party's favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

[1] Such companion briefing includes Plaintiff's Motion for Relief from Judgment [Dkt. # 83], Plaintiff's Motion for Partial Summary Judgment ("MPSJ")[Dkt. # 129], Response in Opposition to Abbott's Motion for Summary Judgment on Causation, Response in Opposition to Defendant's Motion to Exclude Causation Testimony Under Federal Rule of Evidence 702, and Response in Opposition to Defendant's Motion to Exclude the Testimony of Michael Hamrell, Ph.D.

II. SECTION 82.007 DOES NOT BAR PLAINTIFF'S CLAIMS.

Newton's third law of motion holds that for every action there is always an equal and opposite reaction. With respect to the defense bar's wholesale distortion of *Twombly*[2] and *Iqbal,*[3] which has resulted in the addition of routine Rule 12(b)(6) filings to the pharmaceutical defense playbook, this bedrock principle of physics is equally applicable to the science of litigation. This litigation tactic that seeks to prematurely forestall plaintiffs from ever having any benefit of discovery, or other token opportunity to develop their case, is, at its heart a double edged sword. For while it might prove ultimately successful in some cases, in others, it can result in the defendant losing their inevitable Rule 56 summary judgment motion(s) before they are even filed. If plaintiffs are forced to martial evidence to prove they have a viable lawsuit under the auspices of Rule 12(b)(6), then that same evidence is likely to create fact issues. And if it creates fact issues, then summary judgment is undeniably inappropriate. This is exactly the case with respect to Abbott's Civil Practice and Remedies Code ["CPRC"] § 82.007 defense.

In two separate orders, this Court has written extensively on CPRC § 82.007. [Dkt # 39, 62.] In the second Order, the Court ultimately reversed its prior denial of Abbott's Rule 12(b)(6) motion and dismissed Plaintiff's failure-to-warn claims based on the Fifth Circuit's then recent opinion in *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, 672 F.3d 372 (5th Cir. 2012). *See* Order dated March 6, 2012 at 24. However, the Court's stated concern about creating an "insurmountable barrier for many plaintiffs" by prematurely dismissing lawsuits under a statute that requires *evidence* to rebut an *evidentiary* presumption without any benefit of discovery, proved prescient in this instance. Order dated November 8, 2011 at 26-27. Dkt. # 39. After discovery on Plaintiff's then

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[2] *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007).

[3] *Ashcroft v. Iqbal*, 556 U.S. 662 (2009).

sole remaining contract claim, Plaintiff was able to develop a factual record and present evidence to the Court of the applicability of statutory exceptions. After consideration of this evidence, the Court reinstated Plaintiff's failure-to-warn claims noting that the evidence presented was "sufficient to raise a fact issue" under § 82.007. Order dated December 2, 2012 at 7. Dkt. # 114.

Thus, although Plaintiff believes she is entitled to summary judgment on Abbott's § 82.007 defense under at least two enumerated statutory provisions, *see* Plaintiff's MPSJ, as the Court has noted, it has already been presented with evidence to raise a fact issue to establish an exception under § 82.007(b)(3). "Once evidence contradicting the presumption has been offered, the presumption disappears and is not weighed or treated as evidence." *Ackermann v. Wyeth Pharmaceuticals*, 471 F. Supp. 2d 739, 749 (E.D. Tex. 2006) *aff'd*, 526 F.3d 203 (5th Cir. 2008). Thus, regardless of whether Plaintiff is awarded summary judgment on § 82.007 or Abbott's motion is denied, as it should be, the presumption has "disappeared" in this case based on the record before the Court. And it cannot be resurrected simply because Abbott now files a Rule 56 motion.

A. Plaintiff is Entitled to Summary Judgment on Abbott's § 82.007 Defense Based on Off-Label Promotion. Plaintiff has previously chronicled this evidence both in her Motion for Relief from Judgment [Dkt. # 83] and her MPSJ [Dkt. # 129]. That being said, Abbott's principal argument in this section of its brief is a reliance upon favorable, and isolated, portions of the record facts. Unfortunately for them, and unlike the statutory presumption, record evidence of off-label promotion does not simply disappear because Abbott cites to evidence that it perceives as favorable.

1. The record facts clearly supports off-label promotion. Despite assertions to the contrary, Plaintiff relies upon much more than just the call notes that, in and of themselves, create a question of fact. She also relies upon the testimony of the prescribing physician. This testimony shows that the off-label promotion actually reached the prescribing physician. *Ebel v. Eli Lilly,* 536

F.Supp.2d 767, 777 (S.D. Tex. 2008) (Plaintiff must show that off-label promotion actually reached the prescribing physician.). In this instance, the prescriber, Dr. Jovan Popovich, not only confirmed that Abbott sales representatives were encouraging him to use Humira early in RA but that they *made no distinction between severity or disease*. Plaintiff's MPSJ at ¶¶ 6-8; 38-39. This latter point is significant.

It is true that Dr. Popovich testified he understood "early RA" to equally refer to severity or duration. In so doing he confirmed his understanding was that "early RA" can be understood to mean severity. However, the FDA places the onus on the manufacturer to be clear in its promotional activities with respect to off-label promotion regarding disease severity. *Id*. at ¶ 38. In fact, this sort of "blurring of the lines" and "Broadening of Indication/Misleading Communication of the Limits of Indication" is specifically over-promotion within FDA's guidelines. *See* Exhibit R to Plaintiff's MPSJ at 3. Additionally, and a veritable twin to the Psoriasis over-promotion campaign where Abbott minimized the need for failure of lesser therapies, *id*., neither the sales call notes nor the after-the-fact, self-serving Abbott employee testimony mentions anything whatsoever about ensuring any promotion for use in "early RA" was limited to only *after* DMARD therapy failure.[4] Even if viewed in the best possible light for Abbott, its sales tactics with Dr. Popovich were playing on the ambiguity of "early RA." However, given the FDA's stringent view of such sales tactics, at this juncture, it would be improper to reward Abbott with summary judgment for aggressive market.

Abbott's reliance upon Mr. Fuller's testimony regarding his HERO promotional activities is curious at best. Plaintiff has already addressed the over-promotion components of asking Dr.

[4] Sales representative Fuller candidly admits that promoting Humira without including both moderate to severely active RA and inadequate response to DMARD therapy would be off-label over-promotion. Exhibit A at 26:23-27:13 (Deposition of Cedric Fuller) [FILED UNDER SEAL, hereinafter "FUS"]. When asked, he did not deny encouraging Dr. Popovich to prescribe the drug for patients not meeting HERO, he simply stated "I don't recall." *Id.* at 55:2-5. Tellingly enough, and unless counsel missed it, nowhere in its motion does Abbott relay to the Court the actual, and appropriate, indication for Humira at the time of Plaintiff's prescription.

Popovich to prescribe Humira for patients not appropriate for HERO in her Motion to Vacate at 5-11. However, Mr. Fuller testified that he doesn't remember HERO. Exhibit A at 35:7-9: 55:2-5 [FUS]. And *he did not deny* encouraging Dr. Popovich to prescribe Humira for patients not fitting the study protocol. *Id*. He simply could not recall one way or the other his behavior. *Id*. But the contemporaneously created call notes are not so equivocal. They expressly state what Fuller was encouraging Dr. Popovich to do.[5]

The bottom line is that while it may well be medically useful to treat RA early in the disease course, regardless of duration or severity[6], at the time of Plaintiff's prescription, neither "early" nor "mild RA" was an approved indication. Nor was it appropriate for a patient to take Humira if she had not *already* failed DMARD therapy. Thus, paying Dr. Popovich to write Humira prescriptions for patients with early RA who did not fit the HERO trial (that expressly required moderate to severe RA) and making no mention of DMARD therapy failure is, *ipso facto*, off-label promotion.[7] As such, § 82.007(b)(3)(A) is satisfied.

2. Mrs. Murthy's use of Humira was off-label. Abbott's arguments regarding off-label use are an ill-advised attempt to usurp both the statute and the testimony of Dr. Eric Gershwin. Dr. Gershwin's supplemental report and deposition, in-and-of itself, is evidence of off-label use. Exhibit B at 353:25-354:12 (Deposition of Dr. Eric Gershwin) ("...I'm opining is that at

[5] In any event, Abbott's executive Vice President confirms, it was entirely inappropriate for Mr. Fuller to be discussing clinical trials with Dr. Popovich during a sales call. Plaintiff's MPSJ at ¶ 30.

[6] This is exactly the point that Dr. Gershwin is making in the portion of his testimony that is cited by Abbott. Equally true is that he did not believe Plaintiff to have moderate or severe RA, nor had she failed lesser therapies. *See* section II.A.2., *infra*.

[7] *See also* Plaintiff's Reply in Support of Motion for Relief from Judgment at 5-7, and arguments/exhibits contained therein. Dkt. # 98.

that given moment in timer [Plaintiff's] disease was mild.").[8] Nowhere does the statute require that the *prescribing physician* admit his prescription was off-label. Dr. Gershwin alone satisfies this prong of the analysis.

Dr. Gershwin, the Chair of Rheumatology and Immunology at UC Davis, examined all of Plaintiff's medical records. This included both the objective testing and the subjective notes made by Dr. Popovich. [Dkt#85-1] at 1. He noted that Dr. Popovich's records did not contain global assessments of Mrs. Murthy. Exhibit B at 335:16-23. Nor do the medical records reflect or otherwise support Dr. Popovich's deposition testimony with regard to disease severity. *Id*. at 345:21-348:3.[9] This analysis from a highly credentialed rheumatologist is utterly relevant to the issues before this Court. It is equally admissible evidence of off-label use. Plaintiff has satisfied § 82.007(b)(3)(B).

3. Mrs. Murthy's *injuries* were caused by Abbott's over-promotion. The third prong of the § 82.007(b)(3) analysis reads as follows: "the claimant's injury was *causally related* to the recommended, promoted, or advertised *use* of the product." (Emphasis added.) This Court has interpreted this provision as requiring evidence that "the off-label promotion caused the prescribing physician to prescribe the drug to plaintiff for that off-label use." *Murthy v. Abbott Laboratories*, 4:11-CV-105, 2012 WL 6020157, 3 (S.D. Tex. Dec. 3, 2012). It did so without citation for the interpretation.

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[8] *See also Id.* at 330:14-331:14 ("Well, look, there are always exceptions, and I'm sure somebody will agree otherwise. But I think that as I look at the records, my opinion is that she did not have moderate rheumatoid arthritis. At least the way it was described in the records. And I didn't see an instrument to confirm it. I didn't see any standardization....I continue to maintain in a clinical trial objective criteria, subjective criteria that are standardized are required since the physician is being compensated.").

[9] Dr. Gershwin had no opinion with respect to the standard of care *vis-a-vis* Dr. Popovich's treatment of Mrs. Murthy. He simply believes that a forensic review of the records reveals that this woman did not have moderate to severe RA nor had she failed DMARD therapy.

With great respect, Plaintiff suggests that the plain language of § 82.007(b)(3)(C) requires evidence, not that the off-label promotion caused the physician to prescribe the drug, but rather, that Plaintiff's injuries *were caused by her use* of the drug for off-label purposes.[10] This is consistent with Plaintiff's arguments in her Motion for Relief from Judgment [Dkt. # 83 at 13-14.] And it is consistent with the plain language of the statute.

As such, the expert reports of Dr. Gershwin, and board certified oncologist, Dr. Dean McCracken, provide evidence that Plaintiff developed lymphoma due to her use of Humira. [Dkt. # 78-2 and 78-1].[11] Such evidence of causation fulfills the statutory requirements for an off-label exception and warrants a denial of Abbott's summary judgment under § 82.007. *Burton v. Wyeth-Ayerst Laboratories Div. of Am. Home Products Corp.*, 513 F. Supp. 2d 719, 733 (N.D. Tex. 2007)(Denying summary judgment on issue of causation because expert report was "some evidence" of causation.).

In the alternative, assuming this Court's maintains its interpretation of § 82.007(b)(3)(C), and Plaintiff is required to produce evidence that the off-label promotion caused the prescription, the record facts still present sufficient evidence for the application of the (b)(3) exception.

This Court has already written at length about its concerns regarding direct payments to physicians for prescribing medication. *See* Order dated 3/6/12 at pp.17-18. Because Dr. Popovich had a monetary incentive to prescribe Humira to as many HERO patients as he could, in conjunction

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[10] *But see McKay v. Novartis Pharmaceuticals Corp.*, 2013 WL 1278025 (W.D. Tex. Mar. 28, 2013) and *Lucas v. Abbott Laboratories*, 2013 WL 2905488 (N.D. Tex. June 13, 2013) whereby these courts cite to this Court's decision in *Murthy* for interpretation of § 82.007(b)(3)(C). Significantly, the discussion of this exception in *Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767, 777 (S.D. Tex. 2008) *aff'd,* 321 F. App'x 350 (5th Cir. 2009), as cited by Abbott on page 20 of its motion, simply states plaintiff must present evidence that the off-label promotion "actually reached the prescribing physician." It does not concern the "causal" question presented in the third prong of the exception in any regard. Nevertheless, Plaintiff has produced significant evidence that Abbott's off-label promotional efforts actually reached Dr. Popovich. *See* section II.A.1., *supra*.

[11] Exhibit B at 458:5-9; 458:25-465:18 (Humira can cause lymphoma); Exhibit C at 27:20-28:7; 66:12-66:16 (Deposition of Dean McCracken) (Plaintiff's use of Humira caused or contributed to her lymphoma.).

with evidence that Mrs. Murthy was not an appropriate HERO clinical trial patient and the fact that Abbott call notes document that at that point in time its sales representatives were encouraging him to use the drug off-label and for patients not meeting HERO criteria,[12] there is sufficient evidence to present a question of fact on this "causal" question. Moreover, if the evidence is read in the light most favorable to Plaintiff, as the Court is required to do, then summary judgment is inappropriate. A jury could reasonably view these facts as causing Dr. Popovich to prescribe this drug to Plaintiff. At minimum, Plaintiff is entitled to this inference and, as such, the exception applies and summary judgment for Abbott should be denied.

B. Section 82.007(b)(4) Equally Defeats Abbott's Section 82.007 Defense in this Case. Abbott brazenly, and without citation to any precedential support, proclaims § 82.007(b)(4) to only apply to doctors. In so doing, they completely ignore the fact that § 82.007 is entitled "Products liability." Equally telling, the plain language of § 82.007(a) does not limit or otherwise distinguish between "different defendants" *vis-à-vis* the exceptions. Rather, the entirety of the statute is applicable to all. CPRC 74, in contrast, is entitled "medical liability" and illustrates how the legislature acts when it intends to identify "physicians." Moreover, § 82.007(b)(5) utilizes the very same verbiage, *i.e.,* "defendant," in discussing use of a drug before FDA approval. Certainly this use of "defendant" does not mean physicians. Section 82.007(b)(4) is equally applicable to drug makers.

[12] Reliance upon Mr. Fuller's deposition testimony nearly nine years after the fact is hardly the stuff of summary judgment. The man testified he only vaguely recalls Dr. Popovich or any contact with him. Exhibit A at 28:5-16 [FUS]. He could only recall Dr. Popovich being friendly, and either would not, or could not, identify any specific recall of specific communications. *Id*. And although Mr. Fuller no longer works for Abbott, he was represented in deposition by Abbott lawyers. *Id.* at 19:18-21:8. He reviewed his call notes with counsel for Abbott prior to his deposition in this case. *Id.* Further, the off-label promotion component of this case was highlighted to him and he was focused in his discussions with Abbott lawyers on the most significant call notes. *Id.* Even at that, he had no recollection of Humira's indication other than "rheumatoid arthritis." *Id*. at 23:11-24:4.

Second, as chronicled in Plaintiff's MPSJ, Abbott undeniably controlled every single task, and the details thereof, that it assigned to Dr. Popovich under the clinical trial protocol. *See* Plaintiff's MPSJ at 18-21. Plaintiff will not further repeat those arguments. Suffice to say, the simple label of "independent contractor" is not dispositive of the matter and the Court must look deeper. *Id.*[13] Equally significant is that the agreement signed by Dr. Popovich expressly provides that Abbott will indemnify him from any liability for injuries sustained by study subjects through participation in the study or use of Humira. Exhibit D at ¶ 15 (Clinical Study Agreement) [FUS]. Such indemnity includes costs of litigation, defense, and compensatory damage awards. *Id.* The contract equally does not expressly disclaim any agency between the parties.

The cases Abbott relies upon are as unavailing as its arguments. *Abney v. Amgen, Inc.*, 443 F.3d 540, 547 (6th Cir. 2006) was a breach of contract case decided under Kentucky law in which Plaintiffs were trying to force the drug maker to continue to provide them medication under a clinical trial protocol. Additionally, the study investigators, unlike this case, drafted the actual protocol at issue. *Id.* at 548-49. Kentucky has a variety of factors for the Court to consider but no "supreme test" as is the law in Texas. *Id.*[14]

Finally, there is nothing irreconcilable with a physician's duty to individually evaluate each patient and an agency finding by this Court. Dr. Popovich's interactions, in acting on behalf of, and for, Abbott's ultimate benefit, were governed completely by the clinical trial protocol drafted by

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[13] Citations to 21 C.F.R. 312.60 on page 22 of Abbott's Motion actually work against Abbott as it clarifies that Dr. Popovich was required to completely conform to the study protocol designed, and provided to him, by Abbott.

[14] *Suthers v. Amgen, Inc.*, 372 F. Supp. 2d 416, 425 (S.D. N.Y. 2005) was the same fact pattern as *Abney* whereby Plaintiffs were seeking continuation of a clinical trial in order to continuing taking study medication. There was no analysis of agency principles under New York law in the case other than a simple citation to "independent contractor" language in the clinical trial agreement. So too, *Vinion v. Amgen Inc.*, CV 03-202-M-DWM, 2005 WL 6763338 (D. Mont. Nov. 9, 2005) *aff'd,* 272 F. App'x 582 (9th Cir. 2008)(Ruling under Montana law where plaintiffs were seeking free medication after conclusion of clinical trial; oral promises of doctor did not bind company.). No such issues are present in this case. Nor does this case concern any other law except Texas.

Abbott and provided to him. Just because a physician works for a corporation does not mean he stops practicing medicine. He simply practices medicine for the benefit of the company. And while Dr. Popovich was most certainly not a "mere dispensary," he followed the orders given to him by Abbott and felt compelled to do so under the terms of his employment. *See* Plaintiff's MPSJ at 18-21. In sum, § 82.007(b)(4) is equal grounds to deny Abbott's motion.

C. *Lofton's* Holding that the Exception of Section 82.007(b)(1) is Preempted Compels a Conclusion, Under Texas State Law, that the Rule of Section 82.007(a) is Likewise Preempted. Plaintiff is acutely aware of this Court's ruling on her Motion for Reconsideration, Dkt. # 66, and her arguments and authorities concerning the severability of § 82.007(b)(1). Out of respect for the Court she will not repeat them here. However, she does adopt and reiterate them in this pleading in order to preserve them. The case of *Millard Anderson, Jennifer Anderson, Individually and as Next Friends of CBA, a Minor v. Abbott Laboratories,* No. 12-11016*,* is currently pending before the Fifth Circuit. It is a Humira personal injury case that was lost by Plaintiffs based on § 82.007. The issue of severability was fully preserved and briefed, and will be argued to the Fifth Circuit. Because the *Lofton* court specifically did not foreclose that § 82.007(b)(1) is not severable from § 82.007(a), 672 F.3d at 380-381, there is a high likelihood this Court will receive guidance on this issue in the near term. As such, Plaintiff's expressly maintain the arguments she has previously raised, pending *Anderson*.

D. Without the Withheld/Misrepresented Exception in Section (b)(1), Section 82.007 No Longer Conforms to Federal Regulatory Law, But Actually Conflicts With It. This argument is different from that presented in section I.C. It focuses on the fact that without the § 82.007(b)(1) exception, the statute completely frustrates federal regulatory law. As such, *Abbott* is precluded from relying upon § 82.007 under the *Lofton* court's interpretation of it. In other words,

as well as preventing the extension of a presumption of non-liability under state law to companies that did not comply with their federal regulatory duties § 82.007(b)(1) performs the critical function of making § 82.007 consistent with federal law. Indeed, without this exception, the presumption in Subsection (a) omits a critical component of federal regulation. Under sub-section 82.007(a), the presumption applies when the drug is accompanied by "warnings or information . . . approved by the United States [FDA]."

As the Supreme Court has emphasized, however, the mere inclusion of the labeling approved by FDA does not discharge a brand-name drug manufacturer's regulatory duty under federal law. Brand-name drug manufacturers such as Abbott have a duty to "ensur[e] that [their] warnings remain adequate as long as the drug is on the market." *Wyeth v. Levine*, 555 U.S. 555, 571 (2009). Federal regulations expressly provide that "[t]he labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved." 21 C.F.R. § 201.80(e). To comply with this directive, federal regulations give drug companies like Abbott the power and the duty to add adequate warnings *without prior FDA approval*. *See Levine,* 555 U.S. at 568, 571; 21 C.F.R. § 314.70(c)(6)(iii)(A).[15] When drug companies exercise this power, they must provide to the FDA "a full explanation of the basis for the change" in labeling. 21 C.F.R. § 314.70(c)(3). Under federal law, therefore, a brand-name drug manufacturer withholds required information when it fails to comply with its regulatory duty to add or strengthen its warnings.

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[15] The addition of appropriate warnings by drug companies such as Abbott is an integral component of federal regulation. FDA "his limited resources to monitor the 11,000 drugs on the market." *Levine,* 555 U.S. at 578. The insufficiency of its resources is particularly acute after it has approved a drug for marketing. "There is widespread agreement that resources for postmarketing drug safety work are especially inadequate and that resource limitations have hobbled the agency's ability to improve and expand this essential component of its mission." *Id*. at 578-79 n. 11 (quoting Institute of Medicine of the National Academies, *The Future of Drug Safety: Promoting and Protecting the Health of the Public* 193-94 (2007)).

As enacted, TEX. CIV. PRAC. & REM. CODE § 82.007 parallels federal law. Subsection (b)(1) recognizes the federal regulatory scheme by refusing to extend the presumption of non-liability in Subsection (a) when the drug company has failed (intentionally or not[16]) to comply with its regulatory duties under federal law "before *or after* pre-market approval or licensing of the product." *Id*. (italics added). Although the other exceptions in § 82.007 also specify circumstances in which courts should not apply the presumption of non-liability, only the "withholding/misrepresenting" exception in subsection (b)(1) conforms the Texas statute to the requirements of federal regulatory law.

If *Lofton* is correct that federal law preempts the very provision that incorporates a drug manufacturer's post-approval regulatory duty under federal law into § 82.007 – and this Court has already expressly followed *Lofton* – the presumption of non-liability that remains actually *conflicts* with federal law. The remaining presumption would "freeze" the drug's label at a certain point in time, effectively eliminating the drug company's duty under federal regulations to keep its label current.[17] As the Supreme Court has explained, this contradicts the "central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times." *Levine*, 555 U.S. at 570-71. Without subsection 82.007(b)(1), § 82.007 conflicts with federal law. Focusing appropriately on legislative intent, *see* Motion for Reconsideration at 6-13, this court cannot conclude that the Texas legislature intended to enact a statute that conflicted with federal regulatory law. *See* Tex. Gov't Code § 311.023(5) (in construing a statute, the court may consider the

[16] Note that Subsection (b)(1) does not turn on whether the withholding or misrepresentation of information was intentional.

[17] Abbott advocates just such a "freezing." Abbot Motion at 6-7 (Discussing FDA approval of label and warning information). Sadly, this is understandable. Abbott ignored its federal regulatory duty with respect to the very risk that manifested in Mrs. Murthy, choosing instead to rely upon class-labeling. However, class labeling does not alter Abbott's duty to independently warn of the dangers surrounding use of its drug nor does it alter federal regulations allowing drug makers to *sua sponte* make label changes. More, *anon*, section IV, *infra*.

consequences of a particular construction). Given *Lofton*, this Court should invalidate § 82.007 in its entirety.

III. THE LEARNED INTERMEDIARY DOCTRINE DOES NOT BAR PLAINTIFF'S CLAIM.

Plaintiff has previously addressed the facts concerning the learned intermediary doctrine in her MPSJ. She will principally rely upon that briefing in order to spare the Court further reading. However, she will respond to Abbott's specific arguments herein.

A. The Lymphoma Warnings were Inadequate. Although Abbott argues that the simple mentioning of a "risk" in a label ends the inquiry, that is not the law. For when a warning is misleading or ineffective as to the true risk, and such inaccuracy induces a doctor to do something he would not otherwise do, then a court "cannot say that no reasonable jury could conclude that a warning was inadequate." *McNeil v. Wyeth*, 462 F.3d 364, 368 (5th Cir. 2006)(reversing summary judgment). In such a circumstance, summary judgment is inappropriate.

The Fifth Circuit's discussion in *McNeil* is instructive in this instance. In *McNeil*, like this case, the operative label warned that use of the drug "may produce" the specific risk at issue. *Id*. at 366. And like here, the company provided some information about the rate at which the side effect could occur. *Id*. at 370. Yet, despite mentioning the very risk at issue and even warning of a purported rate of occurrence, the Court found that the drug company had a duty not to be misleading or ineffectively warn about the risk. *Id*. For "the mere statement that the risk increases with use does not put a physician on notice that the increase in risk is of a completely different order of magnitude and class of risk." *Id*. Under such circumstances, a jury could readily find that the label was misleading as to the risk, rendering it ineffective, and therefore inadequate. *Id*. The *McNeil* court reiterated that a "proven" causal relationship is irrelevant with respect to the duty to adequately warn and that arguments defending a lack of warning based on a purported lack of clinical trial data are

unavailing: "Texas law, however, does not absolve a manufacturer, as a matter of law, of a duty to warn on grounds that no existing studies or clinical trials prove actual causation." *Id*. Association evidence, *i.e.,* "anecdotal case reports," present enough evidence to raise genuine issues of material fact. *Id. citing Jordan v. Geigy Pharms*., 848 S.W.2d 176, 182 (Tex. App.–Fort Worth 1992, no writ).

In this instance, Plaintiff's MPSJ chronicles nearly the exact same fact pattern. Despite the label mentioning lymphoma, Dr. Popovich was still confused as to whether the drug itself increased the risk. Plaintiff's MPSJ at ¶¶ 18-29, 35-36. The label misleadingly suggested the risk was "not known" despite the fact that internally Abbott recognized a very distinct risk based on use of Humira itself and was confidentially informing its sales staff of that risk. *Id.* However, the sales staff was not disseminating this real warning information to doctors. *Id*. Rather, it was instructed to not "bring it up" and to place the onus on the disease, not the drug. Exhibit E at 1 (Email dated 10/11/04) [FUS]; Exhibit F at 11 (Sales Toolkit) [FUS].

The reason the sales staff was not discussing lymphoma with doctors is a very simple and obvious one: marketing. At the time of Humira's launch in early 2003, it was the third biologic to come to market. Exhibit G at 17:5-20:18 (Deposition of Jim Smith). As such, it was playing catch up to its direct competitors, Remicade and Enbrel. Any increased warning information was seen internally as a commercial threat.

This is not simple conjecture by Plaintiff's counsel. It is documented fact, although the facts have been cast under the veil of secrecy. On October 11, 2004, in the context of a discussion on how to disseminate warnings regarding Humira, Abbott management placed "high priority" on the marketing message. Exhibit E at 1 [FUS]. It was a deemed a "high priority" because "J&J got a 3% stock hit last week attributed to the Remicade label change on lymphoma." *Id*. Thus, when the

lymphoma label was changed in 2005, Abbott needed a "communication strategy" on how to communicate new malignancy warning information for the commercial success of Humira. Exhibit H at 2 (Kent Email, 09 Sep 2005). Management was leery of raising the "threat-level" of any relationship between Humira and malignancies in the eyes of the "public/physicians" based on the changes in the warning and creating a "commercial problem." *Id*. Abbott's approach to the malignancy "problem" was to use reporting rates that were either more favorable, or less clear, and to instruct "sales reps" to spend "30 seconds" on the issue, but "only when asked." *Id*. at 3. Further, Abbott's scientific presentors were told not to "proactively" get into discussions of safety but rather should only present the "usual" information. *Id.* at 1.

This is entirely consistent with the facts of this case. Although Dr. Popovich believes he should, "by definition," have been informed of label changes by sales representatives, when repeatedly asked he had no specific recollection of any Abbott sales representative ever bringing any malignancy or lymphoma warning change to his attention. Exhibit I at 193:5-194:7 (Deposition of Jovan Popovich, M.D.). He simply could not say one way or the other. And consistent with Abbott's marketing plan to handle the "problem" of increased lymphoma warnings, he never asked. *Id*.[18]

The cases cited by Abbott are unavailing. *Brumley v. Pfizer, Inc.*, 149 F. Supp. 2d 305, 313 (S.D. Tex. 2001) simply cited *Rolen v. Burroughs Wellcome Co.*, 856 S.W.2d 607 (Tex. App.—Waco 1993, writ denied) without any analysis or discussion for its holding. Further, in

[18] Abbott, at multiple points, cites isolated snippets of deposition testimony from two of Plaintiff's experts for the proposition that before 2006 there was not enough evidence for a causal link between Humira and lymphoma. Abbott goes too far with such an argument. What this argument highlights is that doctors in the public domain were uninformed about risk information that Abbott was well aware of as evidenced by the internal discussions of definitive risk described above and in Plaintiff's MPSJ that predate 2006. Additionally, as neither Dr. McCracken nor Dr. Gershwin worked for Abbott, they, like the medical community surrounding them, had no access to Abbott's internal documents, discussions, and acknowledgment of the definitive link. All they could review was favorable open source material that Abbott used to create confusion on the issue to its competitive advantage. Equally true is that, unlike Abbott, these experts have no duty to adequately warn or disseminate safety information about Humira. For Abbott to now use its superior knowledge of its confidential understanding of risk as a litigation sword is hypocritical at best.

Brumley, the physician unequivocally testified that not only was he fully aware the drug *itself* could cause the problem, but the warning expressly "*contraindicated*"[19] the use of the drug in the plaintiff's patient type. *Id*. at 312-313. Further, the doctor also specifically instructed the patient on how to prevent the very side effect at issue. *Id.* at 313. This is clearly not the case at bar wherein Dr. Popovich was unaware Humira, could in fact, cause lymphoma outside any risk posed by RA.

Rolen v. Burroughs Wellcome Co., 856 S.W.2d 607, 609 (Tex. App. 1993), upon which the *Brumley* court relied, is a curious cite for Abbott. While it contains a pre-*Centocor*[20] discussion of the concept of the learned intermediary doctrine, it gives no substantiative thought to, or discussion of, what constitutes an adequate warning. *Id*. at 609-610. Nor does it apply the label at issue to the facts of the case before it. *Id*. What the Court of Appeals *does* plainly state though, is that "Food and Drug Administration approval of the packaging insert is not sufficient evidence, by itself, of the adequacy of the warning." *Id*. at 609 citing *Bristol–Myers Co. v. Gonzales,* 561 S.W.2d 801, 804 (Tex. 1978).

Judge Atlas's opinion in *Gerber v. Hoffmann-La Roche Inc.*, 392 F. Supp. 2d 907, 917 (S.D. Tex. 2005) is equally inapposite. Therein, as in *Brumley,* the specific risk at issue was *contraindicated* for use in patients of the plaintiff's type. Judge Atlas noted that this contraindication "specifically and unambiguously" warned about the circumstances complained of, and directly contraindicated its use in plaintiff. *Id*. at 917. This contraindication was "legally significant."

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[19] A "contraindication" is only used when "the risk from use clearly outweighs any possible therapeutic benefit. Only known hazards, and not theoretical possibilities, can be the basis for a contraindication." FDA Guidance for Industry, Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products – Content and Format," October 2011. Available at http://www.fda.gov/downloads/Drugs/Guidances/ucm075096.pdf.

[20] *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 171 (Tex. 2012), reh'g denied (Aug. 17, 2012).

Humira was not contraindicated for use in RA patients nor was lymphoma, or risk thereof, mentioned in any contraindication.[21]

The ultimate point is that according to the prescribing physician in this case, the Humira warnings did not inform him that the drug *itself* could, in fact, cause lymphoma in his patients. Abbott knew internally that the risk was not "unknown." As such, the label was misleading, ineffective, and ergo, inadequate.

B. Plaintiff has Competent Expert Testimony. Plaintiff has responded more fully in her Opposition to Abbott's Motion to Exclude Dr. Michael Hamrell. But importantly, Abbott fails to mention that Dr. Hamrell's alternate warning also specifically warns that the drug *itself* increases the risk of lymphoma in RA patients: "Humira itself increases the risk for the development of lymphoma beyond [RA] itself. There is an elevated risk." Dkt. # at 15-16. This is significantly more informative than "the risk is not known."[22]

C. Abbott's Inadequate Warning was the Producing Cause of Plaintiff's Injuries. Plaintiff has cited and discussed Dr. Popovich's "causation" testimony in her MPSJ. This is a fact based inquiry. However, Abbott overstates both the law and the record. Dr. Popovich admittedly had some level of awareness of a theoretical association between Humira and lymphoma. Plaintiff's MPSJ at ¶¶ 18-28. However, he unequivocally drew distinction between a possible association and a definitive one. *Id.* And he unequivocally wanted to know if the relationship was more than a possible association. *Id*. Although Abbott knew of a definitive association, it did not inform Dr.

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[21] In FN84, Abbott string cites a series of cases decided under the law of other states. Plaintiff will not address them beyond saying that the law of Texas is what applies to this case. And the law in Texas is clear.

[22] In citing *McNeil, supra*, in FN 85, Abbott utterly misconstrues the Fifth Circuit's teachings. For the court was clear that beyond accuracy, equally important considerations are whether the label was misleading as to the risk *and* the effectiveness of whatever warning information was provided. *McNeil*, 462 F.3d at 368-70 ("[A] jury could infer that the warning was ineffective and therefore inadequate" despite mentioning a specific risk.). Moreover, expert testimony of warning inadequacy was also sufficient to raise a fact issue. *Id.* at 372.

Popovich either via label, Dear Doctor Letter, or investigator materials. *Id*. In short, there is a distinct difference between some mention of a risk and clearly and unambigously telling doctors the risk exists *from use of the drug*. Dr. Popovich's testimony bears this out.

Under Texas law, causation is generally an issue of fact. *Lenger v. Physician's Gen. Hosp., Inc.*, 455 S.W.2d 703, 706 (Tex.1970). Nevertheless, Abbott's initial argument regarding causation *vis-à-vis* prescriber "awareness" of the risk is an incomplete and incorrect interpretation of the law. For under all the cases cited by Abbott, including *Centocor*, the key inquiry with respect to the physician's knowledge of the risk, is whether an adequate warning would have altered the decision to *use* the drug, or the manner in which it was prescribed and used:

> We must go one step forward and determine whether, as a matter of law, the evidence showed that *DR. NAVAR WAS AWARE OF THE RISKS ASSOCIATED WITH THE USE OF SUFENTA* even though the warnings may or may not have been adequate. *Technical Chemical Co. v. Jacobs,* 480 S.W.2d 602. *In other words, even if it be assumed that the warning was defective, would this have altered Dr. Navar's decision, as a learned intermediary, to use the drug SUFENTA?*

Stewart v. Janssen Pharmaceutica, Inc., 780 S.W.2d 910, 912 (Tex. App. 1989)(emphasis added to last sentence). *Stewart* was the precedent cited by the *Centocor* court for its statement regarding physician awareness of risk. The analysis in each and every case cited by Abbott centers upon the physician's conduct and whether an adequate warning would have altered it. Additionally, the question of "awareness" of risk is tied to an understanding that the drug itself can cause the issue not, as Abbott would have this Court believe, some vague idea of association. *See Centocor,* 372 S.W.3d 140 at 171 ("The Hamiltons presented no evidence that Patricia's prescribing physicians or Patricia would have acted differently had Centocor provided a different warning that included post-approval information about lupus-like syndrome."); *Dyer v. Danek Med., Inc.*, 115 F. Supp. 2d 732, 741 (N.D. Tex. 2000)(The only causation evidence before the court was that doctor still used the medical

device after knowledge of new FDA warnings; no direct physician testimony.); *Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767, 779 (S.D. Tex. 2008) *aff'd,* 321 F. App'x 350 (5th Cir. 2009)(Physician testified awareness that drug itself "can cause" complained of side effects.); *Koenig v. Purdue Pharma Co.*, 435 F. Supp. 2d 551, 555 (N.D. Tex. 2006)(Physician testified that side effect at issue was "a typical phenomenon" for patients receiving drug at issue.); *Ethicon Endo-Surgery, Inc. v. Meyer*, 249 S.W.3d 513, 518 (Tex. App. 2007)(Physician testified he "had first hand knowledge of the risk" and "did not need" the product maker to warn him of risks he already knew and had experience with.).[23]

Moreover, if he had been adequately warned that the use of Humira itself could cause lymphoma,[24] Dr. Popovich unequivocally stated in sworn deposition testimony that he would either a) have not prescribed the drug to plaintiff, b) have prescribed her a different medication, and/or c) have warned her about the risk.[25] Plaintiff's MPSJ at ¶¶ 27-29, 36-37. Equally dispositive on the issue of causation is that if Plaintiff had been warned, she would have declined the drug. *Id.* This too is sufficient evidence of learned intermediary causation as it changes the "use." *McNeil,* 462 F.3d at 373.

D. Centocor has *Not* Foreclosed a Direct-to-Consumer Marketing Exception to the Learned Intermediary Doctrine. This issue, too, is addressed in Plaintiff's MPSJ. A couple of additionally points should be made here. The facts of this case are distinct from *Centocor.* And

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[23] Abbott confuses its case facts in its parenthetical explanation of *Ethicon*. The case regarding anesthesiology that Abbott is describing is actually *Stewart, supra.* Therein, the Court of Appeals made clear the key inquiry is whether the physician's conduct would change with an adequate warning.

[24] Abbott argues that Dr. Popovich requires a "proven" standard to change his decision making. This is misleading. He testified unequivocally he would not prescribe the drug if he had known of a "definite association." Plaintiff's MPSJ at 29. The same definite association Abbott was acknowledging internally. *Id.* at 19-25.

[25] Any equivocation in a physician's testimony creates a question of fact and renders summary judgment based on learned intermediary causation inappropriate. *McNeil,* 462 F.3d at 372.

despite Abbott wordsmithing, at no point does the *Centocor* court require "egregious" facts for a direct-to-consumer marketing exception.[26]

As Abbott acknowledges, the Court has already written extensively on its concerns regarding direct payments to physicians and the subconscious effects this may have. The point is that although Abbott deems the more than $8,000 Dr. Popovich received in payment as "small," and a company that makes more than $9.3 billion dollars last year on this drug would view that as a minimal amount,[27] it is not. Additionally, at the time Dr. Popovich was enrolling Plaintiff in HERO, he was still gathering patients for inclusion in this study. He had no idea how many patients he might ultimately enroll, but he did know that Abbott was willing to pay him up to $42,000 if he enrolled enough patients. Exhibit D at 3 [FUS]. Although certainly Abbott views this amount as "small," it is not insignificant.

And while Dr. Popovich unsurprisingly defended his treatment decisions, these types of direct payments are suspect at best in the context of a true, impartial intermediary whose *only* interest is the care of his patients. Dr. Popovich appears to be a nice man, but this type of "find a patient and I will give you a check"[28] financial incentive program stands the doctrine on its head.

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[26] *In re Norplant Contraceptive Products Liab. Litig.*, 955 F. Supp. 700, 708 (E.D. Tex. 1997) *aff'd sub nom. In re Norplant Contraceptive Products Litig.*, 165 F.3d 374 (5th Cir. 1999), as cited by Abbott, stands for the unremarkable proposition that the physician should warn his patients in the context of promotional materials. However, as Dr. Popovich so succinctly stated with respect to warning Plaintiff about lymphoma: "I cannot tell something that I don't know." Plaintiff's MPSJ at ¶ 27.

[27] *See* Abbott's 2012 Annual Report at 49. Available from Abbott's website at http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9MTc1NTkwfENoaWxkSUQ9LTF8VHlwZT0z&t=1

[28] This is the exact descriptor used by a fellow HERO clinical investigator to describe the HERO trial. Exhibit J at 255:14-256:7 (Deposition of Dr. Franklin Adams). Dr. Popovich was only a small part of Abbott's $3.8 million dollar physician financial incentive program loosely styled as the HERO study. Exhibit K at 4 (HERO Payment Schedule) [FUS]. Although Dr. Popovich would not go so far, Dr. Adams, in retirement, was quite candid about HERO:

> Let me make one comment here. I never – this study, and I have never had a situation quite like that in my whole career at this quote unquote, HERO Study. And I wasn't happy with it, and I wasn't proud of it. It just was what they came up with and that was the only way I could access patients into this drug. And most --

Abbott's IRB/study monitor based arguments are equally unavailing. As Dr. Hamrell makes clear, the IRB and monitors depend on the entity with the most information when crafting an informed consent form. *See* Plaintiff's Response in Opposition to Abbott's motion to exclude Dr. Hamrell at 21. Without full information from the sponsor, the IRB/monitor cannot approve an adequate informed consent. Whatever logic underpins the learned intermediary doctrine is utterly absent because both the doctor and the IRB/monitor rely upon the drug company to provide them and accurate complete information. When the drug company is vested with the superior knowledge and withholds that information from the individuals who are tasked with protecting study subjects, using those uninformed entities as a litigation shield is unfair and nonsensical. The learned intermediary doctrine should not apply when the sponsor has not adequately warned either the IRB, study monitors, or the principal investigator. And in this instance, it is clear that no amount of Abbott provided materials, study protocol, labeling, or IRB informed consent warned Dr. Popovich this drug can actually cause lymphoma in his patients.

IV. ABBOTT IS ALWAYS RESPONSIBLE FOR THE CONTENT OF ITS LABELING, AND AS SUCH, PLAINTIFF'S CLAIMS ARE NOT PREEMPTED.

While acknowledging the "demanding" nature of any purported federal preemption defense, Abbott not only relegates this portion of its arguments to page 32 of its brief, but also, completely ignores the seminal case on preemption, *Wyeth v. Levine*. For irrespective of FDA action, or inaction, the "central premise of federal drug regulation is that the manufacturer bears responsibility

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> you asked about the -- I would like to defend myself here. Most drug studies are not compensated on find a patient and I will give you a check. They are compensated for doing a research project of a double-blind placebo controlled nature that are very valuable studies. And they are scientifically based and yeah, there is compensation for it, but a hell of a lot of work and it is very dedicated work. This is a little obtuse as far as I'm concerned....I guarantee Abbott no longer pays anybody for patients on their pills.

Exhibit J at 255:14-256:7.

for the content of its label at all times." *Levine*, 555 U.S. at 570-71. Class-wide labeling does not obviate any individual drug manufacturer from its duty to "ensur[e] that its warnings remain adequate as long as the drug is on the market." *Id.* at 571.

The single support for Abbott's arguments is the outlier *Dobbs v. Wyeth Pharmaceuticals*, 797 F. Supp. 2d 1264, 1267 (W.D. Okla. 2011).[29] For *Dobbs* is to counsel's knowledge, the only case post-*Levine* whereby any drug company has successfully pursued a preemption defense. And even then, the court's first opinion regarding preemption was reversed and remanded by the Tenth Circuit. *Dobbs v. Wyeth Pharmaceuticals*, 606 F.3d 1269 (10th Cir. 2010). With the sole exception of Dobbs, the overwhelming majority of courts that have confronted "class-labeling" preemption arguments, have found no preemption.[30]

The case of *Forst v. SmithKline Beecham Corp.*, 639 F. Supp.2d 948 (E.D. Wis. 2009) is worth further review. Like other courts before it, *supra* FN 28, the district court addressed the argument that FDA's "exhaustive and repeated review" of the relationship between a class of drugs and a specific side effect in general mandated that FDA would have rejected a warning added by a particular manufacturer. *Id*. at 954. Like the other courts, the district court in *Forst* understood the difference between a class-wide portion of a label applicable to all drugs in the class and the

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[29] The undersigned represented the *Dobbs* plaintiff. The appeal was dismissed pursuant to settlement before the Tenth Circuit could decide the case.

[30] *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387 (7th Cir. 2010)(Finding no preemption despite class labeling because each drug of a class is different and labels are individualized between drugs); *Baumgardner v. Wyeth Pharms.*, 2010 WL 3431671 (E. D. Pa. Aug. 31, 2010) (unpublished opinion) (The Court denied preemption despite class-labeling arguments in ten different cases); *Dorsett v. Sandoz, Inc.*, 699 F. Supp. 2d 1142, 1159 (C. D. Cal. 2010)("A mere possibility that the FDA might not have allowed an enhanced suicidality warning for Prozac, despite allowing it for Effexor and Paxil, is not enough to warrant preemption."); *Aaron v. Wyeth*, 2010 WL 653984,6 (W.D. Pa. 2010) (unpublished decision)(Rejection of drug company argument that FDA's requirement that class warnings mandated that FDA would have rejected attempt by drug company for drug specific warning for its product.); *Colacicco v. Apotex Inc.*, No. 06-3107 (3d Cir. Apr. 28, 2009)(order vacating prior preemption judgment in favor of drug company post *Levine* and remanding to district courts); *Forst v. SmithKline Beecham Corp.*, 639 F. Supp.2d 948 (E.D. Wis. 2009).

individualized duty of each manufacturer to ensure the adequacy of the warnings on its label. "[T]he fact that the agency considered the association between all SSRI's and suicidality on a number of occasions between 1992 and 2004, the time of Mr. Forst's suicide attempt, does not establish that the FDA would not have approved a proposed change in Paxil's labeling." *Id*.

The *Forst* court also considered the drug company's effort to provide "clear evidence" in the form of the amount of interaction between the company and FDA on the issue and the FDA's repeated review of drug company data. *Id.* Significantly, unlike this case, the drug company actually provided evidence that the FDA *denied* proposed language concerning an increased warning specific to that company's drug. *Id.* Nevertheless, the district court denied the drug maker's attempts to use this punitive "rejection" as "clear evidence" that FDA would have "rejected" an earlier attempt to add a different warning to its product:

> In denying the proposed language, the agency did not prohibit all enhanced warnings. Instead, the FDA merely required removal of Paxil-specific language from a particular portion of Paxil's label in favor of uniform class-wide labeling for all SSRI's. The agency's action did not preclude Paxil-specific language changes to other areas of the labeling or prevent GSK from pursuing a label change through submission of a separate supplement.

Id. As *Forst* demonstrates, class-wide labeling does not absolutely foreclosed any additions or enhancements by an individual manufacturer. Significantly, Abbott admits that the FDA expressly allowed each manufacturer to tailor its warning to its data. Abbott's motion at 7. As such, the drug maker's duty remains the same under *Levine* irregardless of class labeling.[31]

[31] *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 873 (7th Cir. 2010), as cited by Abbott in FN 103 of its brief is pure *dicta*. The cited portion is nothing more than judicial speculation of an alternative outcome in a discussion concerning a lawyer's failure to choose the proper cause of action. *Id*.

V. SUMMARY JUDGMENT IS NOT WARRANTED ON PLAINTIFF'S BREACH OF CONTRACT CLAIMS.

Abbott concludes their brief with an attempted *coup de gras* on Plaintiff's case. Unfortunately for them, the record is replete with evidence that forestalls summary judgment on these claims. First, outside the litigation arena, Abbott readily acknowledges and is aware that Humira can cause lymphoma. In fact, they possess internal causality assessments whereby their own investigators and scientists note that Humira patients "probably" developed lymphoma due to Humira use. *See* Plaintiff's *Daubert* Response. Yet, they exert 50 pages of *Daubert* briefing in an effort to convince this Court that despite what the current label states and despite the internal recognition of this side effect, Plaintiff's MPSJ at ¶¶ 18-26, there is no such evidence or data. Given its avowed litigation position, Abbott would never make a concession whereby it agrees Plaintiff's lymphoma was a result of her use of Humira. Regardless, the record is replete with evidence of Abbott's "actual knowledge" and continued denial of any liability for Plaintiff's injuries constitutes bad faith. At minimum, Plaintiff is entitled to the inference.

Additionally, Abbott goes to great lengths to promote that long standing and severe RA is the cause of lymphoma in Humira patients. Exhibit F at 11. They do not have that crutch in this instance, but are simply left with the proposition that this woman who had RA for a very short period, and in mild form, suddenly developed lymphoma. Additionally, although Dr. Popovich said it was possible the drug caused plaintiff's lymphoma, he expressly said he would defer to an oncologist in making the assessment. Exhibit I at 240:22-241:8. Dr. McCracken has opined that Plaintiff's use of Humira caused her lymphoma. *See* FN 11, *supra*.

Moreover, although Abbott does not come right out and state it, Dr. McCracken has also satisfied the second part of the contractual requirement, *i.e.,* that the injuries be related to study participation. Dr. McCracken made clear in deposition that the "cumulative" exposure to Humira,

including the time period in which she was taking the drug for HERO, is what caused Mrs. Murthy's lymphoma. Exhibit C at 33:9-16.

When, as here, "there is unequal bargaining power between the parties and a risk exists that one of the parties may take advantage of the other based upon the imbalance of power," a special relationship exists between the parties. *Laredo Med. Group v. Lightner,* 153 S.W.3d 70, 72–73 (Tex. App.–San Antonio 2004, pet. denied). When this special relationship exists, the parties owe each other a covenant of good faith and fair dealing. *Arnold v. Nat'l County Mut. Fire Ins. Co.,* 725 S.W.2d 165, 167 (Tex.1987). This case represents this exact scenario. Abbott had superior knowledge of the risks of their drug and the ability to self-servingly make contractual determinations about causation such that Plaintiff has no recourse or ability to bargain. In this instance, they owed Plaintiff such a duty and the evidence reflects that they failed to uphold their covenant in an effort to protect their litigation position.[32] They have not done so in this case and the record so reflects.

Conclusion

For all the foregoing reasons, Plaintiff respectfully requests that the Court deny Abbott's Motion for Summary Judgment on Failure-To-Warn and Breach-of-Contract Claims in its entirety.

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[32] Abbott makes a vague argument that plaintiff failed to present her claim to them for evaluation or requested reimbursement. The contract is not only silent about how to present claims, but Abbott's 30(b)(6) HERO designee and study physician admitted that there was no paperwork for making such a claim, that Abbott does not discuss how to make a claim with their clinical investigators or otherwise provide them guidance on how to process such a claim. Exhibit L at 125:3-125:20 (Deposition of Aileen Pangan) [FUS]. If Abbott's own investigators are provided no guidance on how to present a claim and the contract is silent, then how is Plaintiff to do so? Regardless, this lawsuit has been on file for more than two years. Abbott has plenty of "notice."

Respectfully submitted,

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Certificate of Service

I certify that on this 30th day of July, 2013, Plaintiff's Response in Opposition to Defendant's Motion for Summary Judgment on Failure-to-Warn and Breach-of-Contract Claims has been electronically filed with the Clerk using the CM/ECF system, which will automatically send email notifications of such filing to the following attorneys of record:

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